This anticipation rejection also fails because the cited patent cannot constitute prior art under the statute. The cited patent became prior art no earlier than its filing date, which is February 12, 2003, while the relevant steps of the applicants' claimed process were described in their priority application, filed in India on July 24, 2002; see, for example, the process step descriptions on pages 6-9 of Indian application 555/MAS/2002. The hydrogenation in applicants' claim 1 corresponds with the description in steps e) and f) on page 7 of the priority application.

There is no proper legal basis for this anticipation rejection, and its withdrawal is now appropriate.

First Rejection Under 35 U.S.C. 103(a)

This rejection, applied to claims 1, 2, 4-6, and 8-12, was summarized in paragraph 3 b) of the Office Action and is based on a combination of the above-discussed patent to Vidyadhar et al., with U.S. Patent 4,895,841 to Sugimoto et al.

As discussed, above, the Vidyadhar et al. patent does not meet the statutory requirements to be considered prior art, so is not available for rejection of the applicants' claims.

The Sugimoto et al. patent describes a preparation of donepezil hydrochloride that involves hydrogenating 1-benzyl-4-[(5,6-dimethoxy-1-indanon)-2-ylidenyl]methylpiperidine in a tetrahydrofuran solution. However, this reaction is not involved in the applicants' claimed process and the patent does not teach any of the applicants' claim limitations.

As pointed out in the applicants' prior response, an obviousness rejection must be based on finding at least a suggestion of each and every claim limitation in the cited documents. Even if the Vidyadhar et al. patent was available as prior art, no combination of teachings from the cited documents would provide all of the claim limitations, thus rendering the rejection improper. Sugimoto et al., being unrelated to the applicants' claimed process, cannot establish a *prima facie* case for obviousness, and this rejection should now be withdrawn.

Second Rejection Under 35 U.S.C. § 103(a)

This rejection, applied to claims 1, 2, 4-6, and 8-12 and summarized in paragraph 3 c) of the Office Action, was based on a combination of the above-discussed patent to Vidyadhar et al., with U.S. Patent 4,895,841 to Sugimoto et al., an article by Sugimoto et al. in *Bioorganic and Medicinal Chemistry Letters*, and WO 97/22584.

The article by Sugimoto et al. appears to correspond closely with the teachings of the Sugimoto et al. patent. The process Scheme 1 on page 872 of the article pertains to the same process that was taught in the patent for making donepezil. Thus, this document adds nothing that might be relevant to the applicants' claims.

WO 97/22584 discloses the preparation of donepezil, but does not contain any teachings relating to reactions involving the intermediate compound 5,6-Dimethoxy-2-(pyridin-4-yl)methylene indan-1-one that is specified by the applicants' claims. For this reason, the publication does not supply any of the previously noted deficiencies of the other documents cited in the rejection. Its relevance to any of the other cited documents is not apparent, since there is no mention of hydrogenating any compound.

Since no combination of teachings from the applied documents will meet all of the limitations of the rejected claims, this rejection is not proper and should be withdrawn.

Third Rejection Under 35 U.S.C. § 103(a)

This rejection, applied to claims 1, 2, 4-6, and 8, 9, 11, and 12, is summarized in paragraph 3 d) of the Office Action and involves a combination of U.S. Patents 5,606,064 to Lensky and 4,895,841 to Sugimoto et al.

The Lensky patent teaches preparing donepezil by alkylating 5,6-Dimethoxy-2-(pyridin-4-yl)-methylene-indan-1-one with benzyl bromide to form 1-Benzyl-4-(5,6-dimethoxyindan-1-on-2-ylidene)-methyl-pyridinium bromide, then hydrogenating using a platinum dioxide catalyst. This appears to be quite similar to the process of Sugimoto et al., and does not relate to the process being claimed by the applicants.

Since the Lensky and Sugimoto et al. processes are similar, and their combination does not disclose all of the limitations of the claims, this rejection is improper and should not be maintained.

Fourth Rejection Under 35 U.S.C. § 103(a)

This rejection was applied to claims 1, 2, 4-6, and 8, 9, 11, and 12 and was summarized in paragraph 3 e) of the Office Action. It involves a combination of U.S. Patent 5,606,064 to Lensky, U.S. Patent 4,895,841 to Sugimoto et al., and the Sugimoto et al. article in *Bioorganic and Medicinal Chemistry Letters*.

As in the discussion above for the third obviousness rejection, the Lensky and Sugimoto et al. patents are generally equivalent in their disclosures, and do not mention a reaction that is specified in applicants' claims

As discussed above in connection with the second rejection under 35 U.S.C. § 103(a), the article does not seem to disclose anything that adds to the disclosure of the Sugimoto et al. patent. Therefore, this rejection fails because it does not meet all of the limitations of the rejected claims. The rejection should now be withdrawn.

Fifth Rejection Under 35 U.S.C. § 103(a)

In this rejection, all of claims 1-33, as summarized in paragraph 3 f) of the Office Action, the claims were considered to be rendered obvious by a combination of U.S. Patent 5,606,064 to Lensky, U.S. Patent 4,895,841 to Sugimoto et al., the article by Sugimoto et al. in *Bioorganic and Medicinal Chemistry Letters*, and WO 97/22584.

Applicants have pointed out in the discussions regarding the other obviousness rejections how each of these cited documents differs from their rejected claims. Not one of the documents discloses or suggests hydrogenating 5,6-Dimethoxy-2-(pyridin-4-yl)methylene indan-1-one, using palladium on carbon, as is required by both of independent claims 1 and 19. Therefore, these independent claims and all of their dependent claims must be considered patentable over this cited combination of documents.

This rejection is not legally sufficient and should now be withdrawn.

SUMMARY

All of the pending claims have been shown to be patentable over the cited documents, in any combination. An early notice of the allowability of claims 1-33 is respectfully solicited.

If any minor matters remain to be resolved before disposition of the application, please contact the undersigned by telephone or facsimile to arrange for a personal or telephonic interview.

Respectfully submitted,

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